Oncology tech

K091403

Sean Comer, President
Oncology Tech, L.L.C.
5608 Business Park
San Antonio TX 78218
210-497-2100

JUL 2 9 2009

Summary

Trade Name: Mod1T Compensators for Radiation Beam Therapy

Common Name: Compensator

Classification Name: block, beam shaping, radiation therapy

Predicate Device: The predicate device is "Mod1 Compensators for Radiation Beam Therapy", by Symtium Corporation, FDA number: K062781.

Device Description:

The Oncology Tech Mod1T Compensators for Radiation Beam Therapy are used for modulation of beam intensity during radiation therapy. Typically, a brass or aluminum round is used as a basis for the compensator. It is placed into the milling machine and worked into precise X, Y and Z dimensions. The new design of Oncology Tech Mod1T compensators mills out the compensator brass or aluminum walls and adds a high density material. The higher density of the fill material in the compensator walls provides for more attenuation and less radiation transmission at the field edges.

Intended Use of the Device:

The Oncology Tech Mod1T Radiation Beam Therapy Compensator is designed specifically for application in external beam radiation therapy in cancer treatment. The device could be used in this application for all types of cancer treatable by external beam radiation therapy, with a universal application to this patient population.

Technological Characteristics of the Device:

The predicate device for comparison purposes is the "Mod1 Compensators for Radiation Beam Therapy", by Symtium Corporation, FDA number: K062781. The Oncology Tech Mod1T Radiation Beam Therapy Compensator has the same intended use and similar characteristics to the predicate device.

Oncology tech

Determination of Substantial Equivalence:

The attenuation was measured with a Sun Nuclear profiler in the transverse or cross table plane. Each compensator was locked in place in the tray holder accessory for the linear accelerator. The gantry of the linear accelerator was set at 0° so that it was pointing directly towards the floor. A collimator rotation was also at 0°. The test device was placed on the table used to treat patients and carefully aligned with the collimator crosshairs. The table was raised to the distance that was normally used for standard QA measurements according to the manufacturer instructions. Each compensator was irradiated with 100 monitor units of radiation. The transverse plane attenuation for each compensator was then recorded and compared to the brass compensator baseline. These test results are shown in Appendix A, located within the step 20 clinical testing section of this submission. The measurement results show an improvement of the attenuation under the compensator walls for both the 6X and 18X beams. The addition of the high density fill to the compensator walls at the field edge provides greater attenuation of the photon beam at the field edge and less dose outside the field.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Johnie McConnaughhay
Vice President of Engineering
Oncology Tech, L.L.C.
5608 Business Park
SAN ANTONIO TX 78218

JUL 2 9 2009

Re: K091403
Trade/Device Name: ModIT Compensators for Radiation Beam Therapy
Regulation Number: 21 CFR 892.5710
Regulation Name: Radiation therapy beam-shaping block
Regulatory Class: II
Product Code: IXI
Dated: May 12, 2009
Received: May 12, 2009

Dear Mr. McConnaughhay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Sean Comer, President
Oncology Tech, L.L.C.
5608 Business Park
San Antonio TX 78218
210-497-2100

Indications for Use

510(k) Number (if known): K091403

Device Name: _ Mod1T Compensators for Radiation Beam Therapy ___

Indications for Use:

The Oncology Tech precision milled brass/aluminum compensators with tungsten fillings in the compensator walls are used for modulation of beam intensity during radiation therapy.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091403